Community Walking Trials: Comparing Prosthetic Feet

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Protocol: Overview

Individuals with amputations who participated in the motion analysis optional sub-study at the University of Washington also completed forward walking, side-step, and across river rock with usual foot (session 1), and also with the investigational foot with locked and unlocked conditions(session2). The participants rated their experiences using socket comfort score and the socket pressure score.

Control participants recruited to provide information about of performance for people without amputation were asked to complete forward walking, Figure-of-8 Walk Test, Narrowing Beam Walking Test, side-step, and walking across river rock surface as described below. These tests were conducted at a single session.

People with amputations participating in the primary study at the University of Washington (UW) and WillowWood completed the Figure-of-8 Walk Test and the Narrowing Beam Walking Test with their usual foot (session 1), and also with the investigational foot locked and unlocked (session 2, 2-4 weeks after session 1). The participants kept an activity log book with reflection, completed the Prosthesis Evaluation Questionnaire (PEQ) and Comprehensive Lower Limb Amputee Socket Survey (CLASS) questionnaires, and had a semi-structured interview to gather information about community experiences with the investigational foot (between sessions 1 and 2) and with their usual foot (between sessions 2 and 3).

Complete description

Participant inclusion criteria for both groups were: Age 16 and older; any gender, race, or ethnicity; ability to walk more than 400 m on level ground without using a walking aid and without an increase in pain; and the ability to read, write, and comprehend English. Participants will be excluded if they have neurological, orthopedic, or other conditions that significantly alter gait mechanics. Additional inclusion criteria for participants with amputations will be unilateral below knee amputation (LEA) and intact residual limb skin.

If the participant with an amputation was eligible and wished to participate, an appointment was made for the person to come to the University of Washington Motion Analysis Lab in Wallace Hall or WillowWood, in Mt. Sterling, Ohio. The participant met with a researcher and clinical prosthetist to go through the consenting process. At that time, participants completed the demographic data questionnaire.

The prosthetist assessed the condition and fit of the participant's current prosthesis for alignment, fit, and condition. The prosthetist also inspected the participant's residual limb for skin condition. People with significant skin breakdown were eligible to participate. The prosthetist also determined how best to set up the current socket system with the investigational foot at that time.

At the University of Washington, participants could elect to have additional performance tests described in Aim 2. Session 1 was for testing the participant's usual foot. Session 2 tested the investigational foot in locked and unlocked configurations. Control participants attended one motion analysis session.

Aim 2: Motion analysis trials of the investigational foot compared to the participant's usual foot.

The UW conducted optically-based motion analysis using an 8-camera Qualisys motion capture system 4 embedded tri-axial ground reaction force platforms and a river rock-substrate surface that is parallel to the main motion capture space. For all motion analysis tests, 37 retroreflective markers were taped to anatomical landmarks that are compatible with Visual 3-D kinematic modeling software. Motion data are captured at 120 Hz. People using a prosthetic limb rely heavily on vision for balance. Visual-field blocking glasses have been used to reduce pre-planning of steps. In this study we used basketball training, visual-field blocking glasses because they are low weight, comfortable, washable, and completely block the lower half of the visual field. Even with the neck fully flexed, the feet are not visible during gait.

Participants with amputations volunteering for the community walking trials and recruited at the UW had the option to participate in the motion analysis trials during visit 1, and after two-week acclimation with the Investigational foot, at visit 2. Participants also completed the trials with the Investigational foot linkage locked during Visit 2. Timing minimized patient burden. Control participants attended one motion analysis session.

Motion Analysis Tests (An overhead harness/support system, Solo-Step, was used for all motion analysis tests for all participants at UW and for the Narrowing Beam Walking Test. It was not used for the figure-of-8 test). Motion analysis activities were only done at UW, not at WillowWood.

Forward walking. Forward walking was chosen because it is the most common gait pattern and demonstrated that addition of the linkage does not impair forward walking. Participants walked at a self-selected speed on a level surface for 10 m. In the center of the calibrated walking area, the participant stepped on force plates. Marker position and reaction forces were recorded for 2 sequential steps of the prosthetic side for participants with amputations, or matched side for control subjects. After a practice test, 3 tests where the prosthetic side successfully contacts the force plates were recorded.

Side-step. Side-step and river rock tests were chosen because these movements are common during activities of daily living, have been identified as challenges for people using prosthetics and were theoretically improved by the Investigational foot. Participants performed the test in a similar manner to forward walking but instead moved laterally over the 10 m surface and across the centrally placed force plates. The order of side-stepping to the right or left were randomly assigned. Participants were asked not to cross-over their feet. After a practice test, 3 tests in each direction, where the prosthetic side or matched side successfully contacts the force plates, were recorded.

Walking across river rock surface. We chose the river rock (1”-3”) as it would be demanding and likely a tough obstacle for some of the test population, thereby challenging the group and highlighting any changes to performance with the Investigational foot. Visual field blocking glasses prevented selective foot placement. Linear translation of the calculated body center of mass indicates less work of walking and improved stability (related to our goal of more energy-efficient gait). Participants walked in a direct path through the center of the river rock. They wore a safety harness and were attached to an overhead moving protection system. Participants only used the visual field limiting googles during the river rock walking test. After practice tests, 3 tests were recorded.

Qualitative instruments – Motion Analysis

Modified socket comfort score and pressure score. Adaptability of the Investigational foot was theorized to reduce forces acting on the residual limb. Following each test protocol, participants were asked to rate the socket comfort during the activity from 0 to 10 (with 0 being the least comfortable and 10 being the most comfortable imaginable) and pressures of the prosthetic socket on their residual limb during the activity from 0 to 10 (with zero being none and 10 being the highest imaginable). Participants were asked to qualify the score with subjective comments (related to our goal of more comfortable ambulation and reduced torques acting on the residual limb).

Community Walking Trials (CWT) of the Investigational foot.
To assess the benefit of the Investigational foot, a combination of subjective and objective measures were collected following 2- to 4-week periods of use. 21 LEA subjects completed at the UW and another 10 LEA subjects completed at WillowWood. Note that subjects participating in Aim 2 also had the option to complete the Aim 3 portion of the study.

The testing was conducted following an A-B-A design, where the A condition was the subject's existing prosthetic foot and the B condition was the Investigational foot. The study was designed so that all qualitative data were prospectively collected regarding both feet, but the functional tasks were collected in a manner to reduce the laboratory visit burden on the study participants. During the first laboratory visit, subjects completed functional tasks with their existing prosthesis. Next, they were fit with the Investigational foot and sent home for a 2- to 4-week at-home use period. A team member also contacted the participant about one week after they started using the investigational foot to see how things were going and if there were any issues or problems to address (such as is the degree of stiffness appropriate) that may have prompted a re-fitting. If this occurred, the 2- to 4-week at-home use period was re-started, increasing the participant's total amount of time in the study.

During the second visit, subjects repeated the same functional tasks as at the first visit but while wearing the Investigational foot (locked and unlocked linkage). The subjects also completed study questionnaires based on their experiences with the Investigational foot during the at-home use period. At the end of the visit, subjects were re-fit with their original prosthetic foot and completed another 2- to 4-week at-home use period before completing the study questionnaires either online or by mail.

The primary aim of the study was to establish if the user's comfort and satisfaction with the Investigational foot prosthetic foot were improved when compared to the user's existing prosthetic foot. The team used subscales of the Prosthesis Evaluation Questionnaire (PEQ), as well as an extended version of the Comprehensive Lower-Limb Amputee Socket Survey (CLASS). The combination of performance tests, questionnaires, and qualitative information provided information about a variety of potential clinical benefits listed above as well as participant specific observations.

Qualitative instruments – Community Walking Trials- CWT

PEQ Subscales: The PEQ is a 9-scale instrument that has good psychometric properties and has been validated. The PEQ subscales vary from 0 (worst) to 100 (best). PEQ subscales of residual limb health, ambulation, utility, and sounds were selected for this study and comprise a total of 24 visual analogue scale questions. These subscales were selected because the questions included address primary areas of interest to the study team. We expected the Investigational foot to reduce the socket torque generated when walking on uneven surface, therefore we had an interest in capturing the subject's opinion about their residual limb health, ability to ambulate, and how useful they found the prosthetic foot. We also wanted to ensure that adding the motion did not introduce unwelcomed noise, which can be annoying

and embarrassing for the user; therefore, we also wanted to capture opinions regarding the sounds made by the prosthesis.

CLASS: The intent of the CLASS is to provide greater insight into the cause of socket dissatisfaction compared to the Socket Comfort Score. To accomplish this, the CLASS includes 4 subcategories; 1) stability, 2) suspension, 3) comfort, and 4) appearance. Each subcategory contains 3-4 items scored using a 5-point scale that relate to common tasks such as standing, sitting, walking, and ascending and descending stairs. For the purposes of our study, we augmented the information collected from the CLASS by including additional tasks such as walking on uneven ground, side stepping, and turning.

Informal Interviews and Log: Participants' lived experiences using the Investigational foot in comparison to the participant's usual foot were collected using qualitative research methods. During home use of the participant's usual foot and the Investigational foot, participants kept an activity log (completed either in REDCap or on paper) that encouraged descriptions of activities, including strengths and limitations of foot performance. In addition, there was an exit interview using open-ended questions to obtain qualitative data on foot performance and comparisons of foot prostheses. The interviews were audio recorded. Interviews were conducted remotely via Microsoft Teams or Zoom.

The first step in qualitative data analysis involved reading the activity logs and interview transcripts as a complete body of work prior to further analysis. The next 2 steps involved coding the transcripts. The first round of coding, known as open coding, was intended to identify salient content themes, without regard for the compatibility or coherence of codes. This was followed by focused coding and involved grouping the codes identified in the first round into meta-themes or clusters. The research team then discussed emergent themes so that points could be categorized and cross-referenced if they fell into multiple categories. It is important to note that this analytic process was not intended to produce a set of mutually exclusive categories and that many data points were assigned multiple codes.

A secondary aim of this study was to establish that the user's functional performance with the Investigational foot prosthetic foot was improved when compared to the user's existing prosthetic foot. The team used two clinical performance measures to evaluate this aim. The functional tasks completed during the office visit were 12 standardized clinical outcome measures. The tasks that were completed included the 3 x Figure-of-8 Walk Test (F8W) and the Narrowing Beam Walk Test.

Functional Tasks (An overhead harness/support system, Solo-Step, was used for the Narrowing Beam Walking test for all participants at UW location. At WillowWood, there was no harness system.)

Figure-of-8 Walk Test: The F8W was developed to represent walking skills used in everyday life, involving straight and curved paths in both right and left directions. It has been validated in older adult populations with mobility disability. Subjects began the task standing between the 2 cones. The subject walked a figure 8 course 3 times for each condition at their self-selected pace and stopped when they returned to the start position. The outcomes of the test were the time to complete the course and the number of steps taken.

Narrowing Beam Walking Test: The Narrowing Beam Walking Test was developed to measure balance in lower extremity amputees (LEA) and it was validated in LEPU with and without a history of falls. We chose this test because the purpose of the Investigational foot was to create a more stable platform through the addition of the linkage. The test consists of walking across a beam that has 4, 6-foot long sections, each one narrower than the previous one. The narrowing beam is 2" above the floor. At the

UW site, participants wore a safety harness and was attached to an overhead moving protection system. At the Willow Wood site there was no harness system. When ready, the subject began walking along the beam while keeping their feet pointed in the direction of the beam (no side-stepping allowed). Subjects kept their arms crossed in front of their body to eliminate the use of their arms to maintain balance. The distance of the furthest point of contact from the start of the beam was used as the outcome for the test.

Video recording: Participants were video recorded. Video recording improved understanding of balance responses to functional tasks and performance tests, as well as foot mechanical attributes. Video recording was carried out with audio recording depending on camera function.

Statistical Analysis:

All outcome measures of the community walking trials are numeric and were analyzed similarly. Estimates of the means and the 95% confidence interval for all outcomes were calculated. We tested the difference in outcomes between the usual foot and the investigational foot using the paired t-test if the distributions were at least symmetric or using the Wilcoxon rank-sum test otherwise. For the PEQ and CLASS, both of which were collected 3 times (in the A-B-A design), we performed an exploratory analysis using a repeated measures analysis of variance (if assumptions were met) and a visual display of the individual data over time. Significance level was kept at 0.05 for all tests, without adjustment for multiple comparisons, given that this study was exploratory in nature and will provide effect size estimates for further confirmatory studies.

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CONSENT FORM,ASSENT FORM and PARENT CONSENT FORM
An adaptable foot prosthetic device for people with lower extremity amputations – Community experiences

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If you require medical assistance, please contact your usual care provider or call 911. For prosthetics services related to this study, please call Kate Allyn, CPO (206-390-0228). If you elect to see your usual prosthetist regarding the investigational foot, please have them contact Kate Allyn at the telephone number above.

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then, you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for participation in a research study. Participation is voluntary.
- The purpose of this research study is to evaluate an investigational prosthetic foot designed to be adaptable on uneven ground and side-slopes.
- You may want to join this study if you want to help researchers design a prosthetic foot that has features that will make walking easier on uneven or sloping ground. You may *not* want to join this study if you would be

uncomfortable completing questionnaires/interviews, performing walking tests in a laboratory setting, and/or trying out an investigational foot in your home/community activities.

- Duration of participation will be about 4-8 weeks and will include 2 performance/functional tests in the motion analysis lab, use of the investigational foot for 2-4 weeks in your home/community, a daily activity log, questionnaires, and an exit interview. Four additional motion analysis tests are optional.
- You will not directly benefit from this study.
- There is some risk that you may fall, stumble, or lose your balance. The investigational foot could break, make noise, or cause discomfort. Some people feel uncomfortable giving personal information.
- Participation will assist with the development of a better prosthetic foot for the general amputee population.
- There will be no impact to your routine activities or treatment outside of the study.

PURPOSE OF THE STUDY

We have developed a prosthetic foot that is designed to be adaptable on uneven ground and side-slopes as well as for uncertain placement of foot on the ground. The investigational foot may also help to reduce forces acting through your prosthesis socket. The foot has been tested in the laboratory but not out in the community. The purpose of this study is to compare your usual prosthetic foot with the new prosthetic foot during your usual daily activities. We would like to know whether you experience any differences between different foot prostheses.

STUDY PROCEDURES

If you choose to take part in this part of the study, you will be asked to attend three sessions at the University of Washington Amplifying Movement & Performance Lab.

At two of the sessions, you will be asked to do standardized movement tests to test the performance of the feet. You will practice each test to see how comfortable you feel. You can stop any time you want to either to rest, or stop the activity completely. You do not need to do an activity if you don't want to. During all sessions you will be asked to complete questionnaires or answer questions about your activities.

<u>Visit One</u>

At the start of the first session, you and a member of the study team will review this consent form and you will be given as much time as you need to ask any questions you may have. If you agree to proceed, you and the study team member will both sign this consent form. Next, you will be asked to complete a questionnaire about personal characteristics such as your age, length of time you have been using a prosthetic foot,

and your level of mobility. Questionnaires will take approximately 20 minutes to complete. You do not have to answer every question.

A licensed prosthetist will evaluate your current prosthetic foot prior to walking on the test surfaces, will check the skin of your leg, and ask you questions about pain or problems with the fit and alignment of your usual prosthesis.

Next you will complete two performance/functional walking tests using your own prosthetic foot. You will be able to practice each test before data is recorded.

Performance/functional walking tests:

Figure-of-8 Walk Test: For this test you will walk at your own pace three times in a figure-of-8 pattern around two cones, placed 5 feet apart. You will have the opportunity to practice, and then the test will be repeated three times. This will take about 10 minutes.

Narrowing Beam Walk Test: For this test, with your arms crossed you will walk across a beam that has 4, 6-foot long sections, each one narrower than the previous one. You will repeat this test three times. This will take about 10 minutes.

Motion Analysis Testing (OPTIONAL)

For these tests, small reflective balls will be attached with tape to several points on your arms, legs, and torso. These reflective balls are used by software through cameras mounted around the room to measure motions of the legs, arms, and trunk.

While you are walking, we will ask you to wear special glasses that block the lower part of your vision.

An overhead support system and body harness will be used to keep you from falling if you lose your balance.

The motion analysis study consists of three different types of activities: 1) forward walking, 2) side-step walking to the right and the left, and 3) walking across river rock surface.

Following each test, you will be asked to rate the socket comfort and pressure of the prosthetic on your residual limb during the activity, using a scale of 0 to 10. You will be asked to qualify the scores you give with subjective comments.

The motion analysis testing session will take about 1 hour.

Community Walking Trials

After completing the two performance/functional tests (and the motion analysis tests, if you have opted to participate in this part of the study), the prosthetist will fit you with the investigational foot. You will have time to make sure the fit is comfortable and ask any questions. You will have the opportunity to try it while walking on flat ground, on uneven ground, and stairs. The prosthetist will again check your skin and ask you about pain and prosthetic performance.

You will be asked to complete a diary/log book to record your daily activities and thoughts about the strengths and limitations, comfort, and challenges of the investigational foot. You can also include other information about how your foot impacts your life activities. The activity log can be completed online or on paper; you will be instructed on how to complete this diary. You will be given contact information so you can get in touch with the prosthetist or the lead researcher if you have any difficulties with the investigational foot while you are using it in your home/community.

You will leave the first study visit using the investigational foot. You will take your usual prosthetic foot home in case you have any trouble with investigational foot and need to return to using your usual foot.

The study team will set up an appointment for visit 2, when you will return with the investigational foot, in 2 to 4 weeks. If you have any questions or concerns regarding the study before visit 2, you can contact Kate Allyn at the number above. A team member will also contact you about one week after you start using the investigation foot to see how things are going. There is the possibility that the decision may be made to re-fit you with a different version of the investigational foot that will be better suited to you (for example, a defferent level of stiffness). If this happens, the at-home use period of your participation will be extended for another 2- to 4 weeks.

Visit 2: (2 to 4 weeks after visit 1)

At visit 2, you will return to the UW Amplifying Movement & Performance Lab.

During visit 2 you will hand in your diary/ log book to study staff (if completed on paper).

You will be asked to complete the PEQ questionnaire. This questionnaire asks questions about your residual limb health, your ability to ambulate, how useful you found the investigational foot, and whether the foot caused any unwelcome noise/sounds. You don't have to answer any questions you don't want to. This will take about 10 minutes to complete.

You will also be asked to complete the CLASS questionnaire. This questionnaire asks for your feedback about the stability, suspension, comfort, and appearance of the investigational foot. You don't have to answer any questions you don't want to. This will take about 5 minutes to complete.

There will be an interview to clarify your experiences using the investigational foot. One of the research team members will ask you open-ended questions about your experience with the investigational foot. We will ask you questions such as when you experienced any discomfort, if you had any slips or falls, and how confident you felt using the new foot. You don't have to answer any questions you don't want to. The interview will be audio recorded and transcribed verbatim to allow the research team to analyze your feedback. This will take about 15 minutes to complete.

If you participated in the motion analysis activities during visit 1, your will be asked to repeat the tests using the investigational foot. To determine if the mechanical linkage is effective, you will ask you to repeat the same tests, but the linkage will be locked. The motion analysis tests will take about 1 hour 30 minutes to complete.

All participants will be asked to repeat the figure-of-8 test and narrowing beam tests with the investigational foot linkage in both locked and unlocked positions.

After completing the two performance/functional tests (and the motion analysis tests, if you have opted to participate in this part of the study) with the investigational foot, the prosthetist will fit you with your usual foot, check alignment, check your skin, and ask you about pain and prosthetic performance.

You will be given a new diary/log book to record your daily activities and thoughts about your usual foot (if you are using the paper version).

The study team will set up an appointment for visit 3, when you will return in 2 to 4 weeks' time.

If you have any questions or concerns regarding the study before visit 2, you can contact Kate Allyn at the number above.

Visit 3

At visit 3, you will return to the UW Amplifying Movement & Performance Lab and return the daily activity log book to study staff (if you are using the paper version). You will be asked to repeat the PEQ and CLASS questionnaires for your usual foot and to repeat the interview for questions about your experiences using your usual foot in comparison to the investigational foot.

Visit 3 will take about 30 minutes.

RISKS, STRESS, OR DISCOMFORT

There is some risk that you may fall, stumble, or lose your balance. We do not know if the risk of falls with the investigational foot will be greater or less than with your usual foot. Falls and stumbles can cause serious injury. If you are injured, take appropriate steps to treat your injuries. Also, contact Kate Allyn within 24 hours if possible. Understanding the way falls happen is especially important, whether a fall happens with your usual foot or the investigational foot.

Prosthetic feet can break. We do not know the potential for breakage of the investigational foot in the community. Engineering software, mechanical tests, and a professional engineer have evaluated the strength of the investigational foot, but it has not been tested by people in the community before. You will have your usual foot to replace the investigational foot if necessary.

Socket-to-limb contact forces and motion can cause skin breakdown. We do not know if the investigational foot will be better or worse than your usual foot. This problem can be reduced by regular skin checks. Alignment and socket fit are also very important; using

a different foot may change alignment and socket comfort. Shoe choice can be limited by prosthesis alignment. Heel height changes prosthetic alignment. It is possible that the new investigational foot will not allow you to wear your usual range of footwear.

The investigational foot may make noise compared to your usual foot. It has several moving parts that might have friction and produce sounds. We do not know if the foot will make noise under conditions such as getting wet or dirty. The foot covering is intended to minimize the risk of moisture and dirt getting into the joints but it might happen. You will be given information on cleaning the foot if this happens. If you have any concerns about your prosthetic foot while participating in this study, please contact Kate Allyn at the number above, and she may be able to treat you or will refer you to the appropriate practitioner.

Some people feel uncomfortable giving personal information. All questions are optional.

This study is not intended to substitute for your usual, ongoing, professional prosthetist care. Please consider your schedule for the next 4 to 8 weeks. We are hoping that you will be doing similar activities over this time period so that you can compare your usual foot to the investigational foot. Having plans for something that might drastically change your activities would make comparisons difficult.

Travel, outside the greater Seattle area, would limit the researchers from assisting with prosthetic issues should they arise.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Taking part in this study is voluntary; you can choose not to take part. To have your prosthetic foot and your mobility reviewed by a licensed prosthetist, please contact a clinic/provider that is convenient for you.

BENEFITS OF THE STUDY

You will not directly benefit from this study. We hope the results of this study will help us design better prosthetic feet that can be available to people with amputations.

The team and/or the University of Washington is receiving financial support from the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

Study data will be confidential. There will be links between study data and identifiers that will be kept in separate secured areas. The link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the federal government who needs it in order to audit or evaluate the research;
- Individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- The federal Food and Drug Administration (FDA), if required by the FDA.

OTHER INFORMATION

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

USE OF INFORMATION AND SPECIMENS

Using Your Data in Future Research

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

Payment for participation in the motion analysis testing only will be $50 at visit 1 and at visit 2 (total $100).

Payment for participation in the community walking trials will be up to $400.

- $200 for completion of the 2nd study visit and return of the investigational foot
- $200 for completion of the 3rd study visit

If you decide to end your participation without completing all study sessions:

- $100 if you decide to end your participation in the study between sessions 1 and 2, and you return the investigational foot.
- $100 if you decide to end your participation in the study between sessions 2 and 3, and you return the investigational foot.

The maximum payment for participation is $500 for the 3 study visits and participation in the motion analysis option.

You can opt out of receiving the money if you wish.

Parking will be paid for your study visits.

RESEARCH-RELATED INJURY

If you think you have a serious injury or medical problem, call your usual health care provider or call 911. If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility. It is important that you promptly tell the researchers if you believe that you have been injured due to taking part in this study by calling the study coordinator at 206-543-6995. For prosthetic-related concerns, please call Kate Allyn at: 206-390-0228.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

When subject is a minor:

Printed name of parent	Signature of parent	Date

Copies to: Researcher
Subject
Subject's parent

OPTIONAL VIDEO CONSENT

I understand that the study team requests my permission to make video recordings of the performance/functional tasks and the motion analysis tasks.

____ (initials) I give my permission to allow video recordings.

____ (initials) I do not give my permission to allow video recordings.

Printed name of subject	Signature of subject	Date

When subject is a minor:

Printed name of parent	Signature of parent	Date

Copies to: Researcher
Subject
Subject's parent

OPTIONAL MOTION ANALYSIS TESTING CONSENT

I understand that the study team requests my participation in motion analysis tasks, and I understand that participation is these tasks is optional.

____ (initials) I give my permission to participate in motion analysis tasks.

____ (initials) I do not give my permission to participate in motion analysis tasks.

Printed name of subject	Signature of subject	Date

When subject is a minor:

Printed name of parent	Signature of parent	Date

Copies to: Researcher
Subject
Subject's parent